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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,130	12/03/2001	Takahide Kishimoto	2356/10	4623

7590

05/27/2004

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EXAMINER

LEARY, LOUISE N

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,130

Applicant(s)

KISHIMOTO ET AL.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-69 is/are allowed.
- 6) ☒ Claim(s) 1-6 and 70-78 is/are rejected.
- 7) ☒ Claim(s) 7-18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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1. Claims 1-18 and 21-78 are pending in this application.
2. The rejection of claims 1, 3, 19-53, 58-69 under 35 U.S.C. 112, second paragraph has been rendered moot by the amendment to the claims submitted March 18, 2004.
3. The rejection of claims 19-20 under 35 USC 102(b) as anticipated by Garrow (US 5,668,173) is moot in view of the cancellation of claims 19-20 by the amendment submitted March 18, 2004.

4.) OBJECTIONS AND REJECTIONS:

A.) Objection to the Specification:

The "Objection to the Specification" has been maintained for reasons of record.

Namely, the meaning applicants intended for the phrase "and the like" in the specification can not be determined. Alternatively, the phrase "and the like" includes elements not actually disclosed by the original specification.

Also, the examiner disagrees with applicant's assertion that "the Examiner has not provided a statutory basis for such an objection" because 35 USC 112, first paragraph, requires applicants to present a specification meeting the criteria described below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Correction is required.

5. Applicant's arguments filed March 18, 2004 have been fully considered but they are not persuasive.

A.) The rejection of claims 70-78 under 35 U.S.C. 112, second paragraph, has been maintained for reasons of record.

Claims 70-78 are indefinite due to the omission of instructions for using the kits claimed.

First, claim 70, recites "A reagent kit for homocysteine determination, which comprises at least buffer, transferase utilizing homocysteine and other compound as a pair of substrates, said other compound, and a reagent for analyzing a compound produced by the enzymatic reaction." It is unclear which compound produced by the enzymatic reaction indicates the presence or absence of homocysteine when using the kit claimed. In addition, it is unclear if "said compound," indicates the presence of two ---other compounds--- in the reagent kit.

Secondly, in claims 72 - 78, the phrase "where necessary," implies that further instructions for using the kit may be necessary.

Thus, instructions for using the kits claimed have been deemed a necessary claim limitation to particularly point out and distinctly claim the subject matter applicants

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regard as the invention. Correction is required to comply with the 35 USC 112, second paragraph, statute.

B.) The rejection of claims 1-6 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over van Dijken et al (Archives of Microbiology, V 111(1-2), pp 77-83, (Dec. 1976)(Abstract Only) for reasons of record. The examiner have carefully considered applicant's argument. However, the arguments were not persuasive because the prior art describes a ---formaldehyde dehydrogenase dependent on glutathione and NAD--- as claimed in the present invention. The characteristics described in the instant claims have been deemed inherent features of dehydrogenase derived from *Hansenula* yeast described in the prior art reference absent a comparative showing of unexpected results.

Also, the instant methods use the word "comprises" which is open-ended language that does not exclude the dehydrogenase derived from *Hansenula polymorpha* described in the van Dijken et al abstract. For these reasons applicant's arguments were not persuasive.

6. Claims 7-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claims 54-57 are allowable over the prior art of record.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 571-0966. The examiner can normally be reached on Monday to Friday from 10 to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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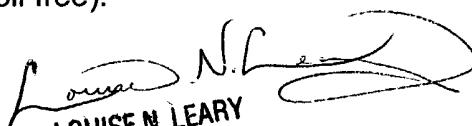
published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY
PRIMARY EXAMINER

May 21, 2004